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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/653,114	05/24/96	FALCK-PEDERSEN	E 19603/233 (CR)
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HM12/0908

EXAMINER

SCHNIZER, R

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

09/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**FILE COPY****Office Action Summary**Application No.  
**08/653,114**

Applicant(s)

**Falck-Pedersen**

Examiner

**Richard Schnizer**Group Art Unit  
**1632**☒ Responsive to communication(s) filed on May 23, 2000☒ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**☒ Claim(s) 1-4, 7-11, 13-15, and 17 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.☒ Claim(s) 1-4, 7-11, 13-15, and 17 is/are rejected.☐ Claim(s) \_\_\_\_\_ is/are objected to.☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152**— SEE OFFICE ACTION ON THE FOLLOWING PAGES —**

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## DETAILED ACTION

### *Continued Prosecution Application*

The request filed on 5/23/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/653114 is acceptable and a CPA has been established. No new arguments have been presented. An action on the CPA follows.

Claims 1-4, 7-11, 13-15, and 17 remain pending in the instant application.

1, 3, 4, 9, 17, 18-20

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

*Amended*

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 15 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record in Paper Nos. 26 and 29, mailed 2/3/99, and 8/23/99, respectively. Briefly, the specification, while being enabling for host cells *in vitro*, does not reasonably provide enablement for host cells *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. Inclusion of the term *in vitro* in claims 14 and 15 would be remedial.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 7, and 14 are rejected under 35 U.S.C. 112, second paragraph, for the reasons of record in Paper Nos. 26 and 29, mailed 2/3/99, and 8/23/99, respectively.

***Claim Rejections - 35 USC § 103***

Claims 1-4, 7-11, 13-15, and 17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kirshenbaum et al, Quantin et al, or Stratford-Perricaudet et al, in view of Huang et al, Choi et al, Keating et al, and Kabigen et al, for the reasons of record in Paper Nos. 26 and 29, mailed 2/3/99, and 8/23/99, respectively.

***Conclusion***

No claim is allowed.

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday-Friday from 7:30 to 4:00 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached at 703-308-2801. The FAX phone number for art unit 1632 is 703-308-0294.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Richard Schnizer, Ph. D.

*Scott D. Pribe*  
SCOTT D. PRIEBE, PH.D.  
PRIMARY EXAMINER